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Minnesota Board of Pharmacy

University Park Plaza
2829 University Ave SE, Suite 530
Minneapolis, MN 55414-3251
www.phcybrd.state.mn.us

Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Actions

No disciplinary actions were finalized by the Minnesota Board of Pharmacy between the dates of June 1, 2004 and September 1, 2004.

Governor Makes Board Appointments

During June 2004, Governor Tim Pawlenty made his appointments for the two pharmacist positions that had technically expired on the first Monday of January 2004.

Board Member Betty Johnson, a retail pharmacist from Elbow Lake, MN, was reappointed to a second four-year term.

Mr Chuck Cooper, who finished his second four-year term in office in January 2004, was not reappointed. Replacing Mr Cooper is Ms Kay Dvorak, a Target Pharmacy district manager. Prior to becoming a district manager for Target, Ms Dvorak had both independent retail and chain pharmacy experience.

The terms of both Ms Johnson and Ms Dvorak will expire on the first Monday of January 2008.

The Board wishes to acknowledge the many contributions Mr Cooper made to the Board over his eight-year term and to thank him for his insightful and articulate discussions of the various issues that came before the Board.

Controlled Substance Dispensing Expanded

During the 2004 legislative session, the statutes relating to who may prescribe controlled substance drugs for filling in Minnesota pharmacies were modified to expand the universe of authorized prescribers.

Prior to August 1, 2004, Minnesota pharmacists were only authorized to fill controlled substance prescriptions written by physicians licensed and practicing in Minnesota or a state adjoining Minnesota (Iowa, North Dakota, South Dakota, and Wisconsin). The new statute, which became effective August 1, 2004, allows Minnesota pharmacists to fill controlled substance prescriptions written by practitioners holding valid Drug Enforcement Administration (DEA) numbers who practice anywhere in the United States.

Extemporaneous Compounding Issues

Over the past several months, the Board has received several complaints, comments, or questions from the public regarding prescriptions they have received that required extemporaneous compounding by pharmacists. The Board has also received numerous phone calls from pharmacists presented with prescriptions that require compounding. Most of the comments and questions and at least one of the formal complaints had to do with expiration dates for compounded pharmaceuticals.

Pharmacists are required to include an expiration date on most dispensed prescriptions. Selecting the appropriate expiration date for compounded products has raised questions among both pharmacists and the public receiving compounded prescriptions.

Pharmacists cannot simply arbitrarily select an expiration date for compounded products. In some cases, manufacturers of products commonly used in extemporaneous compounding have done stability studies and will provide the pharmacists with expiration date information. Other sources of expiration date information may be available from the manufacturers of suspending agents or other vehicles used in preparing suspensions or solutions of certain drugs. On occasion, the United States Pharmacopeia will also have stability data and expiration date information.

The key thing to remember, however, is that pharmacists must have stability data to support the expiration date placed on prescriptions for compounded products. An expiration date cannot simply be arbitrarily selected.

Syringe Law Clarification

The Board office continues to receive questions regarding the current law addressing the sale of syringes and needles in Minnesota. Minnesota's syringe-and-needle law is somewhat complicated, so the following clarification is offered.

Minnesota does not require prescriptions for the sale of syringes and needles for legitimate medical purposes. The law requires the pharmacist making such a sale to use professional judgment in determining whether or not the request for syringes and needles is for a legitimate medical purpose. If the pharmacist determines that the request is legitimate, the purchaser can obtain any quantity of syringes and needles without a prescription.

If the pharmacist determines that the request for syringes and needles is not for a legitimate medical purpose, the pharmacist can still provide up to 10 syringes and needles to the purchaser, but only if the pharmacy is enrolled in the needle exchange program through the Minnesota Department of Health. If the pharmacy is not enrolled in the Department of Health's needle exchange program, then the pharmacist is not allowed to sell any syringes or needles if the pharmacist believes that they will not be used for a legitimate medical purpose.

New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the counter (OTC) medications that contain levels of calcium, magnesium, sodium, or potassium that might be harmful to persons with certain underlying medical conditions. The final rule was effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with certain medical conditions such as heart disease, hypertension, kidney disease, kidney stones, or other medical conditions could worsen their condition upon consumption of these products. For example, OTC use of medications containing potassium may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the exact amount of a particular ingredient in each dose if they contain:

- 5 mg or more of sodium in a single dose,
- 20 mg or more of calcium in a single dose,
- 8 mg or more of magnesium in a single dose, or
- 5 mg or more of potassium in a single dose.

The rules also require warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult their physician before using oral products that contain maximum daily doses of:

- more than 140 mg sodium,
- more than 3.2 grams calcium,
- more than 600 mg magnesium, or
- more than 975 mg potassium.

Currently the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes. Detailed information on the rulings can be found in the Federal Register at www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm and www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm.

FDA Requests Antidepressant Manufacturers to Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory that cautions physicians, their patients, and families and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports, but it is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to change the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlaxafine (Effexor®), and sertraline (Zoloft®). It should be noted that Prozac is the only drug approved for use in children with major depressive disorder. Prozac, Zoloft, and Luvox are approved for pediatric patients with obsessive-compulsive disorder.

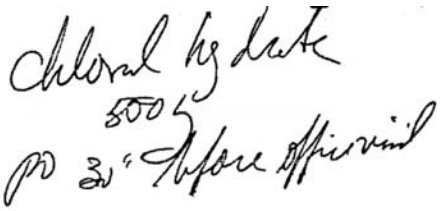
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Further information can be found on CDER's Web site: www.fda.gov/cder/drug/antidepressants/default.htm.

Let Past Experience with Chloral Hydrate Syrup Guide its Safe Use

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Chloral hydrate can be used safely to sedate pediatric patients for diagnostic procedures such as endoscopic procedures, CT scans, or MRIs. However, in several error reports over the years we have seen the sad stories of fatalities that have occurred after excessive doses of the drug were dispensed in error. Typically, deaths have occurred in cases where the order was not clear or when untrained individuals, both staff and parents, were involved without adequate supervision or the knowledge that they were administering an overdose. In some cases, to save time, chloral hydrate has been prescribed for use at home prior to travel to the practice site. In one instance, a 500 mg/5 mL concentration was dispensed instead of 250 mg/5 mL, which also is available. Unfortunately, the dose was prescribed by volume (teaspoonful), which made detection of the twofold overdose impossible. In another incidence, 120 mL of syrup was incorrectly dispensed instead of the prescribed 12 mL. The label instructed the mother to give her child the entire bottle, which she did. Without trained personnel and emergency equipment present to treat these accidental overdoses, the children in both cases died.

Recently the tragedy happened again. A prescription was written for a 17-month-old child; the pharmacist read the directions as "30 cc before office visit" and instructed the mother to give her child that amount. In truth, the physician wanted the child to receive 500 mg 30 *minutes* before the office visit. The double hash-mark symbol (''), which the physician intended to mean minutes, was misread as cc. Actually, a double hash mark stands for seconds; a single hash mark (') is used for minutes. Neither symbol should be used in medicine, however, because not everyone understands their meaning.



Errors also happen in diagnostic areas where technical support personnel often administer oral conscious sedation even though they are not properly trained. In some cases, an ambiguous physician order such as "give chloral hydrate 5 cc prn sedation" or ". . . prn agitation," rather than a specific milligram amount and maximum dose, has led to events where multiple doses of chloral hydrate were dispensed from the supply available to personnel. By the time the child fell asleep, the amount administered was a massive overdose leading to respiratory arrest.

Please consider reviewing your process for dispensing oral liquids used for conscious sedation in children, whether to a medical facility or to a family member. We suggest that the following precautions, in addition to package insert recommendations, be employed. Advise physicians that the drug should not be prescribed by volume (eg, "5 mL," "one teaspoonful," etc). There are two available concentrations of this drug. Instead, the specific milligram dose should be expressed. The prescription should state that it is for pre-procedure sedation. In hospital situations or when pharmacies dispense to health care facilities, prescriptions are best dispensed for each patient in labeled, unit-dose, oral syringes; providing the product in bulk packages as floor stock is less safe. We believe it is safest for pharmacists to *not* dispense prescriptions for patient use in the home when it is for pre-procedure sedation. Should the caregiver receive such a prescription, he or she should be advised that they are safest for the dose to be administered where the procedure will be performed. Official labeling for Versed® Syrup, another drug used for conscious sedation in children, notes that the syrup is intended for use only in monitored settings, never the home. Also, as noted in the product's boxed warning, only health care professionals trained in conscious sedation procedures and authorized to administer conscious sedation drugs should do so. Careful monitoring by direct visual observation is necessary and age-/size- appropriate resuscitation equipment must be readily available. The American Academy of Pediatrics agrees; the Academy's current "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" (*Pediatrics* 2002; 110:836-838) recommend that children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel. These medications should be administered by, or in the presence of, individuals skilled in airway management and cardiopulmonary resuscitation and administered in a health care facility where appropriate monitoring, including continuous pulse oximetry, can be instituted.

One final argument for administering children's sedation on site is to ensure proper timing in case of unpredictable schedule delays.

NABP Releases Updated NAPLEX Blueprint

NABP has released the updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®). The blueprint is available for viewing on NABP's Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers in the entire examination blueprint instead of focusing it within a single competency area as with the current NAPLEX. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

The updated blueprint and competency statements require a new passing standard. However, the NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate's ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX. The new passing standard will go into effect along with the updated blueprint in spring 2005.

For more information about the NAPLEX, contact the Customer Service Department by calling 847/698-6227 or visit the Association's Web site at www.nabp.net.

December 2004 FPGEE Date and Location Announced

On December 4, 2004, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Mateo, CA. Candidates who have been accepted to sit for the December 4, 2004 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE™, a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP's Web site at www.nabp.net.

Continuing Education Reports Due

By the time this *Newsletter* is posted the due date for continuing education (CE) reporting by Minnesota pharmacists will have passed. All Minnesota pharmacists should have submitted their affidavit of CE participation by October 1, 2004, covering the period October 1, 2002 through September 30, 2004.

Those pharmacists that are randomly selected for auditing will be notified during October or early November of the need to submit documentation of the 30 hours of CE required for the two-year reporting period. Pharmacists who have not received a CE audit letter by Thanksgiving of 2004 can feel secure in cleaning out their CE file and discarding the records for the 2002 to 2004 reporting period.

OxyContin Diversion on the Increase in Minnesota

During the last two weeks of August 2004, three armed robberies in which the drug demanded of the pharmacist was OxyContin® were brought to the Board's attention. It would appear that the demand for OxyContin obtained through burglaries and armed robberies – an issue that has become common elsewhere in the country – has finally reached Minnesota.

Pharmacists should be made aware of a program designed to help protect pharmacists, guard against potential robberies and burglaries, and assist law enforcement to apprehend and successfully prosecute criminals. The program is called RxPATROL®. RxPATROL stands for Rx Pattern Analysis Tracking Robberies & Other Losses. RxPATROL is a collaborative effort between industry and law enforcement that is designed to collect, collate, analyze, and disseminate pharmacy theft information. Directed by a senior law enforcement executive and utilizing a sophisticated software platform to analyze theft information for trends and patterns, RxPATROL will gather information from pharmacy theft reports and serve as a clearinghouse to disseminate pertinent leads to the law enforcement community.

Any Minnesota pharmacist that suffers a controlled substance loss through theft or burglary is encouraged to visit the RxPATROL Web site at www.rxpatrol.org and voluntarily complete the theft report form that is available online.

The online theft report does not replace the filing of a DEA 106 form for reporting the loss of controlled substances or the notification of the Board office through the submission of a copy of the DEA 106 form, but it does serve to provide law enforcement with an additional tool to apprehend and prosecute the individuals involved in controlled substance diversion.

Rule Changes Under Consideration

Board members and staff have begun work on a significant package of potential rule changes that will be under development by the Board over the next several months. Some of the proposed changes will be new rules needed to meet changes in federal standards or to address evolving areas of pharmacy practice. Other changes will involve modifications of existing rules or, in a couple of cases, deletions of all or parts of existing rules. Future *Newsletters* will continue to update readers on the specifics of the rule changes being considered. At this point, more than 20 rule sections have been identified for consideration for additions or changes.

The rule making process in Minnesota is a lengthy one and provides ample opportunity for input by affected parties. The Board will undoubtedly be requesting input from the major pharmacy organizations in Minnesota as well as from one or more ad hoc advisory committees prior to formally proposing the changes under consideration. Stay tuned for future developments.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

David E. Holmstrom, JD, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Reneeta C. "Rene" Renganathan - Editorial Manager

MINNESOTA BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc
700 Busse Highway
Park Ridge, Illinois 60068

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